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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Teruo Kirikae

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EXAMINER

KIM, YUNSOO

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

12/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,153	Applicant(s) KIRIKAE ET AL.	
	Examiner YUNSOO KIM	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-28,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/12/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 25-28, 33 and 34 are pending.
2. Applicants' IDS filed on 9/12/08 has been considered.
3. In response to Applicants' arguments filed on 9/12/08, the objection and the rejection set forth in the office action mailed on 3/13/08 (sections 5-7) have been withdrawn.
4. Claim 34 is objected to because of the following informalities: Typographic errors are noted in "Klebsiela" and "Straphylococcus aureus". Appropriate correction is required.
5. Upon further consideration, the following rejections set forth herein.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 25, 28 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting a bacterial pneumonia which comprises assaying an antigen in a sample which can be detected by an antibody that binds to CAP18 or SEQ ID NO:1, does not reasonably provide enablement for a method of detecting the specific bacterial species as recited in claim 34.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

Art Unit: 1644

The claimed invention encompasses a method of detecting a bacterial pneumonia comprising assaying an antigen and an antibody that binds to the antigen. Given that said assaying is carried out immunologically, said assaying method step is forming an immune complex between an antigen and an antibody. The art recognizes a qualitative detection of a specific antigen using an antibody which binds to the antigen.

However, the claimed invention is drawn to a detection of specific bacterial species with an antibody. As taught by Swierzko et al. (J. Med. Microbiol. 2000, vol. 49, p. 127-138, of record), CAP18 is a host peptide and binds to LPS of different bacterial species. LPS from various species have been isolated and binding of CAP18 to the LPS has been studied (p. 128-131). Given that the LPS is found in most bacterial species and CAP18 binds to the LPS, it is not clear how the recited antibody performs the claimed method in a species specific manner to identify a causative bacterium in the bacterial pneumonia. The prior art recognizes that a causative agent for a pneumonia patient is identified by culturing for bacteria with sputum, urine and serum specimens (p. 459 under specimen collection, Miller, 1978, J. Clinical Biology, vol. 7, p. 459-462).

The claimed method as in claim 34 currently is recited without further comprising additional method step to identify whether the patient has a *Klebsiella* or a *Staphylococcus aureus* pneumonia. Therefore, the claimed invention for identifying the type of bacteria is not enabled solely by forming an antigen-antibody complex, especially by the CAP18 antigen binds to the LPS of various bacterial species.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use the claimed method in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 25-28 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bals et al. (Am. J. Respir. Crit. Care. Med. vol. 165, p. 992-995, 2002).

Bals et al. teach a detection of pneumonia infection by assaying a patient sample for the presence of CAP18 in the airways of the patient using an antibody binds to CAP18 (LL37)(abstract, results, p. 992-994). Bals et al. further teach that the pneumonia is associated with a significant increase in CAP18 concentration and is a maker for detection of pulmonary diseases (discussion, p. 995).

As bronchoalveolar lavage fluid is sampled (p. 992, right column), claim 33 is included.

Therefore, the reference teachings anticipate the claimed invention.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim

Patent Examiner

Technology Center 1600

December 15, 2008

/Michael Szperka/

Primary Examiner, Art Unit 1644